

WHAT IS CLAIMED IS:

1                   1.       A sample collection device for collecting a biological sample from  
2 a mammary organ of a patient, comprising:

3                               a breast engaging member constructed of a non-porous material  
4 sized and dimensioned to receive at least a nipple portion of a breast of said patient and  
5 form a suction seal therewith;

6                               a solid phase sample collection medium in fluid connection with  
7 said breast engaging member for receiving a sample of expressed breast fluid; and

8                               vacuum pump means in gaseous connection with said breast  
9 engaging member for generating negative pressure through the breast engaging member  
10 to facilitate breast fluid expression, wherein the sample collection device is a hand-held  
11 breast pump incorporating said breast engaging member and vacuum pump means in a  
12 compact, structurally integrated breast fluid collection apparatus that can be manipulated  
13 and operated with one hand.

1                   2.       The sample collection device of claim 1, wherein said solid phase  
2 sample collection medium is selected from the group consisting of microscopic glass  
3 slides, capillary tubes, collection tubes, columns, micro-columns, wells, plates,  
4 membranes, filters, resins, inorganic matrices, beads, resins, particulate chromatographic  
5 media, plastic microparticles, latex particles, coated tubes, coated templates, coated  
6 beads, coated matrices, or a combination thereof.

1                   3.       The sample collection device of claim 1, wherein said hand-held  
2 breast pump comprises a modular device formed of a plurality of components that are  
3 joined or securable in fixed structural interconnection with one another and may be  
4 partially or completely disassembled to remove or uncouple the individual components as  
5 desired for efficient operation, cleaning, servicing and/or storage.

1                   4.       The sample collection device of claim 3, wherein said modular  
2 breast pump device includes a separate breast engaging member constructed of a rigid or  
3 semi-rigid, non-porous material sized and dimensioned to receive at least a nipple or  
4 areolar portion of a human subject's breast and form a suction seal therewith, wherein

5 said breast engaging member is detachable from one or more interconnecting components  
6 of the hand-held pump device for cleaning and sterilization or to allow for interchanging  
7 of different engaging members to accommodate breast anatomy differences among  
8 patients.

1                   5.       The sample collection device of claim 1, wherein said solid phase  
2 sample collection medium is supported by a support member removably mounted in fluid  
3 connection with said breast engaging member.

1                   6.       The sample collection device of claim 5, wherein said support  
2 member is provided as a removable cassette that can be inserted within said breast  
3 engaging member to be removably mounted in fluid connection therewith.

1                   7.       The sample collection device of claim 5, wherein said support  
2 member supports one or more pads or sheets of absorbent or adsorbent material.

1                   8.       The sample collection device of claim 1, wherein said solid phase  
2 sample collection medium comprises a nitrocellulose membrane.

1                   9.       The sample collection device of claim 8, wherein said  
2 nitrocellulose membrane has a pore size selected to effectively retain whole cells from  
3 expressed breast fluid on a surface of the membrane.

1                   10.      The sample collection device of claim 7, wherein the pad or sheet  
2 is a modified membrane or filter having perforations or slits that disrupt the planar surface  
3 of the membrane or filter to facilitate air passage therethrough and impart structural  
4 flexibility against mechanical perturbation.

1                   11.      The sample collection device of claim 5, wherein said support  
2 member incorporates one or more air channels that pass through a body of the support  
3 member for passage of vacuum pressure therethrough and/or to serve as channels for  
4 passage or breast fluid sample materials between the breast engaging member and a  
5 sample collection housing member of the hand-held breast pump.



3 engages and makes a circumferential airtight seal against the inner wall of the casing  
4 member when the vial is nested within the casing member.

1 20. The sample collection device of claim 14, wherein the removable  
2 reservoir member is gaseously and fluidly connected with the breast engaging member to  
3 facilitate sample collection.

1 21. The sample collection device of claim 14, wherein vacuum  
2 pressure from the vacuum pump means is routed to the breast engaging member through  
3 the removable reservoir member of the housing.

1 22. The sample collection device of claim 21, wherein the removable  
2 reservoir member is modified to include one or more air ports that form a gaseous  
3 connection between a lumen of the reservoir and the vacuum pump means.

1 23. The sample collection device of claim 14, wherein the removable  
2 reservoir member functions as both a conduit for vacuum pressure transmission to the  
3 breast and a receptacle for fluid sample materials to directly collect expressed fluid or as a  
4 secondary collection medium to receive primarily collected sample materials washed or  
5 otherwise transferred from a primary solid phase sample collection medium.

1 24. The sample collection device of claim 14, wherein the removable  
2 reservoir member communicates for fluid and gaseous transmission directly with the  
3 breast engaging member or indirectly therewith by way of air channels in a support  
4 member optionally coupled with the breast engaging member.

1 25. The sample collection device of claim 14, wherein a primary solid  
2 phase sample collection medium fluidly connected with the breast engaging member is  
3 positioned to collect a primary sample of one or more breast fluid components which can  
4 thereafter be washed or otherwise transferred directly or indirectly into the removable  
5 reservoir member without removal or disassembly of the breast engaging member and  
6 reservoir member.

1 26. The sample collection device of claim 25, wherein the primary  
2 solid phase sample collection medium is a nitrocellulose membrane for retaining cells and  
3 other cytological materials on a surface of the membrane.

1                    32.        The sample collection device of claim 30, wherein the reservoir  
2        member is modified to include one or more air ports that form a gaseous connection  
3        between a lumen of the reservoir and the vacuum pump means when the reservoir  
4        member is engaged with the pump device, and wherein the closure means further  
5        comprises secondary closure means to sealably close the air port(s) after sample  
6        collection.

1           33.     The sample collection device of claim 32, wherein said secondary  
2 closure means comprise an adhesive seal or sticker sized and constructed to adhere to an  
3 outer wall of the reservoir member surrounding an air port opening.

1           34.     The sample collection device of claim 32, wherein said secondary  
2 closure means comprises a combined closure and labeling device which functions as a  
3 secondary closure mechanism to seal the air port(s) of the removable reservoir and as a  
4 labeling template to provide a writing surface for sample labeling.

1           35.     The sample collection device of claim 32, wherein said secondary  
2 closure means comprises a combined closure and labeling tab or sticker which may be  
3 directly applied to seal the air port after sample collection having a first, closure-forming  
4 surface for application over the air port to form a seal by juxtaposition or adhesive contact  
5 with an outer wall of the removable reservoir, and a second, labeling surface opposite the  
6 closure-forming surface made of a blank template material suitable for receiving a stable,  
7 ink or graphite imprint thereon.

1           36.     The sample collection device of claim 35, wherein said first,  
2 closure-forming surface bears an adhesive coating resistant to disruption by contact with  
3 aqueous solutions.

1           37.     The sample collection device of claim 32, wherein said secondary  
2 closure means comprises a combined closure and labeling tab or sticker which is pre-  
3 attached to the removable reservoir member in a first, open configuration and can be  
4 manually repositioned or otherwise manipulated after sample collection to a second,  
5 closed configuration to form a seal or closure against the air port(s).

1           38.     The sample collection device of claim 37, wherein said secondary  
2 closure means comprises an adhesive tab or strip folded in the open configuration to form  
3 an inner layer affixed to the reservoir proximate to the air port and an outer layer folded  
4 over the inner layer, said outer layer providing the first, closure-forming surface and the  
5 second, labeling surface, wherein the outer layer can be unfolded away from the inner  
6 layer and wrapped around the reservoir so that the closure-forming surface covers the air  
7 port to form a fluid-resistant closure and the labeling surface faces outward for  
8 recordation of sample data.

1                   39.     The sample collection device of claim 38, wherein the outer layer  
2 is optionally secured in a folded-back position against the inner layer by adhesive  
3 engagement of the labeling surface with the inner layer.

1                   40.     The sample collection device of claim 39, wherein said first,  
2 closure-forming surface bears an adhesive coating that is protected in the open  
3 configuration by folding of an end segment of the outer layer bearing the adhesive coating  
4 back, so that the closure forming surface provides a protective surface to shield the  
5 adhesive prior to closure, whereby the end segment can be lifted and pulled outward to  
6 unfold the end segment to separate the adhesive coating on the closure-forming surface  
7 from the protective surface and to release the outer layer from the inner layer for closing  
8 of the air port(s).

1                   41.     The sample collection device of claim 14, wherein the breast  
2 engaging member includes removable coupling means for removable coupling of the  
3 breast engaging member with a complementary coupling surface of the sample collection  
4 housing.

1                   42.     The sample collection device of claim 41, wherein the sample  
2 collection housing includes an outer casing member and a removable, fluid reservoir  
3 member, and wherein the engaging member can be directly coupled to the fluid reservoir  
4 member.

1                   43.     The sample collection device of claim 42, wherein the breast  
2 engaging member has coupling threads to engage complementary threads of an open end  
3 of the removable reservoir, said complementary threads of the reservoir adapted to  
4 interchangeably receive a cap that sealably engages the reservoir open end.

1                   44.     The sample collection device of claim 43, wherein the removable  
2 reservoir member is a modified cytology vial.

1                   45.     The sample collection device of claim 1, wherein the solid phase  
2 sample collection medium is adjustably mounted relative to the sample collection housing  
3 so that the solid phase collection medium can be controllably moved closer to, or farther  
4 away from, a base of the engaging member of the pump during use.

1                   46.     The sample collection device of claim 1, further comprising a  
2 reciprocating mechanism which adjustably moves the solid phase sample collection  
3 medium in closer, or more distant, proximity to the nipple when the hand-held breast  
4 pump is engaged therewith.

1                   47.     The sample collection device of claim 1, further comprising a  
2 compact vacuum pump housing which structurally and functionally integrates the vacuum  
3 pump with the sample collection housing.

1                   48.     The sample collection device of claim 47, wherein the vacuum  
2 pump housing and outer casing member of the sample collection housing are cast or  
3 molded as a single, integral component of the device.

1                   49.     The sample collection device of claim 1, further comprising a  
2 vacuum pump actuating mechanism connected to a vacuum pump housing of the device.

1                   50.     The sample collection device of claim 49, wherein the vacuum  
2 pump actuating mechanism comprises an actuating lever pivotally connected to the pump  
3 housing.

1                   51.     The sample collection device of claim 49, wherein the pump  
2 housing includes an integral handle opposing an actuating lever pivotally connected to a  
3 base portion of the handle.

1                   52.     The sample collection device of claim 1, wherein the vacuum  
2 pump means comprises a flexible diaphragm member and pump actuation means to draw  
3 the diaphragm member away from a primary vacuum chamber connected with, or  
4 integrated within, the sample collection housing.

1                   53.     The sample collection device of claim 52, further comprising a  
2 vacuum pump housing, wherein the primary vacuum chamber is integrally formed within  
3 the vacuum pump housing proximate the flexible diaphragm member and extends to a  
4 communicating port opening to the sample collection housing.



- 1                   54.     The sample collection device of claim 53, further comprising a  
2     removable fluid reservoir member of the housing modified to include one or more air ports  
3     that form a gaseous connection between a lumen of the reservoir and the communication port  
4     to gaseously connect the lumen of the reservoir to the primary vacuum chamber.

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